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OSTI-LLNL Organizational Structure

Quality Implementing Procedure ID:
OSTI-LLNL-QIP1.0, Rev.0, Mod.0

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OSTI-LLNL ORGANIZATIONAL STRUCTURE

QA: QA

Quality Implementing Procedure ID: OSTI-LLNL-QIP-1.0, Rev.0, Mod.0

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1. PURPOSE

This Quality Implementing Procedure (QIP) describes the organizational structure, functional responsibilities, levels of authority, and lines of communication between the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Office of Science & Technology and International (OSTI) and Lawrence Livermore National Laboratory (LLNL). The OSTI-LLNL Quality Assurance (QA) Program has been established for application on OSTI-LLNL Project activities. The procedure also identifies the interface between the OSTI-LLNL QA organization and the DOE Office of Quality Assurance (OQA), and the independent reporting structure for QA responsibilities.

2. SCOPE

This procedure is applicable to the organizations and personnel directly responsible for establishing and executing work assignments supporting OSTI-LLNL activities. This procedure describes the overall responsibilities of the OSTI-LLNL organization to meet the requirements of the DOE OCRWM *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P, as described in the *OSTI-LLNL QA Plan* and detailed responsibility descriptions defined in OSTI-LLNL-QIPs and OSTI-LLNL-Technical Implementing Procedures (TIPs).

3. PROCEDURE

3.1 Changes to Procedure

The Project Manager (PM) for the OSTI-LLNL Project shall direct the OSTI-LLNL QA Manager to revise this QIP based on DOE or LLNL changes to the organization responsibilities described in Sections 3.4, 3.5 and 3.6 of this procedure. Changes shall be prepared in accordance with the OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*. Reviews shall be performed in accordance with OSTI-LLNL-QIP-6.1, *Document Review*.

3.2 Assignment of Work and Delegation of Authority

The PM retains responsibility for overall implementation of the OSTI-LLNL QA Program. The PM has assigned responsibilities and delegated authority to key OSTI-LLNL staff members as described in Sections 3.4, 3.5, and 3.6 below. Detailed responsibilities for OSTI-LLNL activities are described in applicable OSTI-LLNL Technical Work Plans (TWPs), OSTI-LLNL-QIPs, and OSTI-LLNL-TIPs. OSTI-LLNL TWPs and implementing procedures are reviewed and approved by the PM.

Positions or organizations responsible for establishing and executing the quality program may delegate work and/or signature authority to other positions or

organizations. Such delegation shall be made in writing (e.g., interoffice correspondence, electronic mail, or letter), except in those cases where "or designee" is stated within a QIP or TIP. The positions or organizations making the delegation shall identify the beginning and end dates of the delegation, and shall retain overall responsibility for the delegated work. Documented delegation of authority shall be transmitted to the OSTI-LLNL Records Coordinator for storage in accordance with OSTI-LLNL-QIP-17.0, *Record Management*.

3.3 Resolution of Quality Disputes

Conflicts or disputes involving quality or technical issues arising from a difference of opinion between OSTI-LLNL personnel shall be referred to successively higher levels of management within LLNL and ultimately be resolved by the PM or designee. Quality-related disputes involving OSTI-LLNL personnel, and OCRWM OQA personnel that cannot be resolved shall be referred to successively higher levels of management within the OSTI-LLNL Project. If satisfactory resolution cannot be obtained at that level, the dispute shall be submitted to OCRWM for resolution.

3.4 OSTI-LLNL Organizational Relationships, Responsibilities, and Interface with DOE/OCRWM Quality Assurance Organization

The OSTI-LLNL Project is executed within the LLNL Energy & Environment Directorate (EED), as part of the Yucca Mountain & Repository Science Program (YMRSP). The organizational structure of the OSTI-LLNL Project and the relationship with OCRWM OQA and OSTI is shown in Attachment 1, OSTI-LLNL Organizational Structure.

Overall responsibilities for key OSTI-LLNL staff members are described in this Section, and in Sections 3.5 and 3.6 below. Detailed responsibilities are described in OSTI-LLNL QA implementing procedures. Throughout the program, quality shall be achieved and maintained by those who have been assigned responsibility for performing the work. Quality achievement shall be verified by persons or organizations not directly responsible for performing the work.

3.4.1 Program Leader Yucca Mountain and Repository Science Program (Project Manager)

The LLNL Associate Director (AD) of EED has the overall responsibility for the management of the OSTI-LLNL Project. The EED AD delegates the responsibility and authority for the OSTI-LLNL Project to the EED YMRSP Manager, who hereafter is referred to as Project Manager (PM) throughout the OSTI-LLNL-QA Program. The PM reports to the EED AD, and has overall responsibility for ensuring the achievement and maintenance of quality on the OSTI-LLNL Project. The line of communication between the PM and OCRWM is through the DOE Technical Task Representative and the OQA representative. The PM shall issue and maintain a policy statement directing mandatory compliance with the OSTI-LLNL QA Program documents by

OSTI-LLNL personnel. Specific responsibilities of the PM include, but are not limited to:

- A. managing the OSTI-LLNL technical work subject to the OSTI-LLNL QA Program, and ensuring implementation thereof.
- B. authorizing the establishment of and approving the *OSTI-LLNL QA Plan*, and implementing procedure documents;
- C. providing overall direction for project planning and assigning technical work;
- D. providing final resolution on conflicts or disputes within OSTI-LLNL involving quality; for quality-related disputes between organizations, providing final resolution on conflicts together with the Director, OQA, as applicable.
- E. ensuring OSTI-LLNL staff are adequately trained to OSTI-LLNL QA Program requirements to ensure the highest quality work products.
- F. interfacing with the Principal Investigators (PIs) and the OSTI-LLNL QA Manager to ensure quality matters are adequately addressed.
- G. keeping the DOE Technical Task Representative apprized of work progress.

3.4.2 Deputy Project Manager

The Deputy PM, when assigned, reports to the PM, and has responsibility for oversight of the YMRSP QA Technical Support Staff, for assigning qualified Checkers, Technical and QA Reviewers to review scientific documents, and for other tasks as delegated by the PM.

3.5 LLNL Yucca Mountain and Repository Science Program Quality Assurance Technical Support

The OSTI-LLNL QA Manager and QA technical support staff are a part of the Technical and Administrative Support Department within EED and report to the PM/DPM on the OSTI-LLNL Project. QA staff under the direction of the PM/DPM and the QA Manager, work in collaboration with the PIs and scientific staff to ensure the implementation of the *OSTI-LLNL QA Plan* and OSTI-LLNL QA implementing procedures. QA staff members are responsible for assisting in the integration of quality requirements into technical activities. QA staff, together with line technical staff, is responsible for identifying problems relating to quality and for working with other technical/administrative personnel to define and implement solutions to problems.

3.5.1 Quality Assurance Manager

The PM shall designate a QA Manager for the OSTI-LLNL Project who has appropriate knowledge and experience in management and QA. The OSTI-LLNL QA Manager is responsible for directing the implementation of the OSTI-LLNL QA Program for application on the OSTI-LLNL Project. The QA Manager position is at the same or higher organizational level as the PIs on the OSTI-LLNL Project. The QA Manager interfaces with project personnel on quality matters as necessary, and will refer any quality-related unresolved conflicts and disputes to the Deputy PM for further resolution, and if needed, to successively higher levels of management as described in Section 3.3. The responsibilities of the OSTI-LLNL QA Manager include, but are not limited to:

- A. being sufficiently independent from cost and scheduling considerations and have the organizational freedom to communicate to all levels about QA matters;
- B. communicating regularly with the PM, and DPM regarding the effectiveness and adequacy of the OSTI-LLNL QA Program, and serve as primary liaison with the DOE/OQA Representative on QA matters;
- C. having the responsibility and authority to coordinate the OSTI-LLNL QA Program to ensure the development, implementation, and maintenance thereof; being responsible for reviewing, interpreting, and approving the OSTI-LLNL QA procedures to assure they meet LLNL and DOE QA requirements; directing the accomplishment of QA program training thereof;
- D. having no other assigned responsibilities unrelated to LLNL QA Programs that would prevent full attention to QA matters;
- E. identifying quality problems, initiating, recommending, or providing solutions to quality problems; initiating, preparing/coordinating responses to Conditions Adverse to Quality (CAQ) and verify the disposition, including stopping work when it has been determined that conditions warrant this; resolving difference relative to quality matters, escalating them to the DPM or the PM, as necessary;
- F. overseeing the proper establishment and implementation of the OSTI-LLNL QA Program, reporting QA program information to management, QA staff, and other affected organizations as appropriate; overseeing software, scientific notebook, records coordination, OSTI-LLNL training activities, and all QA support functions overall;
- G. reviewing changes to the QARD and revising OSTI-LLNL QA Program documents as applicable; identifying where within the OSTI-LLNL QA Program QARD requirements are met, noting applicability and exceptions

to requirements, and including justification thereof; working with PIs to establish TIPs, ensuring imposed QA requirements are met; and

H. coordinating with OQA to plan, schedule, and conduct OQA QA audits that verify the execution of the QA Program.

3.5.2 Technical Data Coordinator

The Technical Data Coordinator is responsible for submitting OSTI-LLNL key data to the appropriate database within the OSTI-LLNL Technical Data Management System (TDMS) and for coordinating technical reviews of all data submittals in accordance with OSTI-LLNL-QIP-SIII.3, *Submittal and Incorporation of Data to the Technical Data Management System*.

3.5.3 Procurement Coordinator

The Procurement Coordinator is responsible for coordinating procurement activities between OSTI-LLNL staff requesting quality-affecting services and procurements in accordance with OSTI-LLNL-QIP-4.0, *Procurement Document Control* and OSTI-LLNL-QIP-7.0, *Control of Purchased Products and Services*.

3.5.4 Software Coordinator

The Software Coordinator is responsible for providing software configuration management control and coordinating activities between OSTI-LLNL staff in accordance with OSTI-LLNL-SI.0, *Software Management*. The Software Coordinator works with the developers and users of software on OSTI-LLNL quality-affecting work to ensure the development and installation processes proceed according to the OSTI-LLNL QA Program and technical requirements for software.

3.5.5 Training Coordinator

The Training Coordinator, based on input from the PM/DPM, the QA Manager, or PI, is responsible for ensuring that OSTI-LLNL staff have the necessary QA training, by coordinating and providing the training as deemed necessary, in accordance with OSTI-LLNL-QIP-2.0, *Indoctrination and Training of Personnel*. In addition, the Training Coordinator is responsible for ensuring that OSTI-LLNL staff has documented position descriptions and that required education and experience have been verified in accordance with OSTI-LLNL-QIP-2.1, *Establishment and Verification of Required Education and Experience of Personnel*.

3.5.6 Scientific Notebook Coordinator

The Scientific Notebook Coordinator is responsible for issuing scientific notebooks, overseeing the initial entry process, coordinating technical and compliance reviews thereof, and updating LLNL information in the

centralized OSTI-LLNL Scientific Notebook Register in compliance with OSTI-LLNL-SIIL.0, *Scientific Notebooks*.

3.5.7 Records Coordinator

The Records Coordinator is responsible for maintaining all applicable records developed under the OSTI-LLNL QA Program in accordance with OSTI-LLNL-QIP-17.0, and for providing for controlled distribution of OSTI-LLNL TWP's, QIP's, TIP's, and other documents that prescribe quality-affecting activities in accordance with OSTI-LLNL-6.0, *Controlled Documents*.

3.5.8 Measuring and Test Equipment Coordinator

The Measuring and Test Equipment (M&TE) Coordinator is responsible for preparing and maintaining an up-to-date list of M&TE, coordinating internal and vendor calibration services, overseeing all other M&TE processes in accordance with OSTI-LLNL-QIP-12.0, *Control of Measuring and Test Equipment and Calibration Standards*, and maintaining and submitting all associated records thereof.

A single individual within the YMRSP QA technical support staff may be responsible for more than one of the coordinator responsibilities described above. QA functions also include numerous other activities such as preparation of planning documents, checking of technical documents, production of technical work products, coordination of document reviews, etc. which are assigned to qualified staff members, as needed, to assist scientific staff in meeting all requirements of the OSTI-LLNL Project.

3.6 Line Management Technical Personnel

Technical personnel include Technical Area Leaders (TALs), PIs, and Scientific Staff. As depicted in Attachment 1, technical work performed by LLNL on the OSTI-LLNL Project is divided into research areas of expertise. The hierarchy suggested in the organization chart conveys levels of responsibility. All LLNL individuals performing technical work on the OSTI-LLNL Project report directly to the PM, DPM, or designated PI.

Scientific personnel are responsible for carrying out assigned OSTI-LLNL tasks and satisfying all technical and quality requirements including those specified in contracts, purchase documents, or management directives. Scientific staff, together with OSTI-LLNL QA technical support staff, is responsible for identifying problems relating to quality and for working with other scientific/QA personnel to define and implement solutions to problems.

3.6.1 Technical Area Leaders

TALs are experts in their research area who serve as the point of contact for associated internal and external inquiries, and are responsible for coordinating/developing research interests/activities that are categorized by their common nature (e.g., ambient field testing, thermal testing, modeling) across departments within EED. TALs serve as informal advisors to the PM

on topics in these areas and may represent LLNL, as the PM's designee, on committees pertaining to their areas of expertise. In some instances TALs may also be PIs. In these instances, the TAL technical and quality responsibilities would be the same as that of a PI.

3.6.2 Principal Investigators

PIs report to the PM and are responsible for managing the technical work of their projects and ensuring that it is carried out in a technically defensible and cost-effective manner under sound QA practices. A PI may work alone on a project, but more commonly is supported by a number of scientific staff that are assigned to various project tasks. PI responsibilities include but are not limited to:

- A. establishing the quality standards for their projects/activities in compliance with the OSTI-LLNL QA Program and supplementary OSTI-LLNL QA procedure requirements;
- B. assuring that plans, TIPs, scientific notebooks, software, and/or other appropriate documentation are developed, approved, and followed for applicable quality-affecting activities;
- C. assuring implementation of quality requirements and providing supplementary training for applicable quality-affecting activities;
- D. assuring that applicable OSTI-LLNL TWP, and OSTI-LLNL QA implementing procedures are included in appropriate requests for proposals, bids, contracts, subcontracts, and purchase orders.

3.6.3 Scientific Staff

Scientific staff report to their assigned PI and are responsible for conducting their activities on the OSTI-LLNL Project in a technically defensible and cost-effective manner that includes compliance with the OSTI-LLNL TWP and OSTI-LLNL QA implementing procedures (i.e., QIPs, TIPs).

3.6.4 Contractors

All organizations that support or perform OSTI-LLNL quality-affecting activities, shall comply with the requirements of the OCRWM QARD and any applicable OSTI-LLNL QA Program documents or another OQA approved QA program meeting the QARD as specified by written agreement. Written agreements shall be used to document interfaces between such outside organizations and the OSTI-LLNL Project.

3.7 Training Requirements

OSTI-LLNL personnel who conduct activities subject to DOE/RW-0333P QARD requirements shall be trained in the applicable OSTI-LLNL-QA Program Documents as deemed appropriate by the PM/DPM, together with the PI and QA Manager.

4. RECORDS

The records listed in Section 4.1 shall be collected and maintained in accordance with OSTI-LLNL-QIP-17.0, as individual records or included in a records package.

4.1 QA Records

Delegation of authority

4.2 Non-QA Long Term Records

None

4.2 Non-QA Short-Term Records (Three years or less retention)

None

5. RESPONSIBILITIES

The overall responsibilities of OSTI-LLNL staff and interface with DOE/OQA are as described in Section 3 of this procedure.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

CAQ	Condition Adverse to Quality
DOE	U.S. Department of Energy
DPM	Deputy Project Manager
EED	Energy & Environment Directorate
LLNL	Lawrence Livermore National Laboratory
M&TE	Measuring and Test Equipment
OCRWM	Office of Civilian Radioactive Waste Management
OQA	Office of Quality Assurance
OSTI	Office of Science & Technology and International
PI	Principal Investigator
PM	Project Manager
QA	Quality Assurance
QARD	Quality Assurance Requirements and Description
QIP	Quality Implementing Procedure
TAL	Technical Area Leader
TDMS	Technical Data Management System

TIP	Technical Implementing Procedure
TWP	Technical Work Plan
YMRSP	Yucca Mountain & Repository Science Program

6.2 Definitions

None.

7. REFERENCES

DOE/RW-0333P, *Quality Assurance Requirements and Description*

OSTI-LLNL-QIP-2.0, *Indoctrination and Training of Personnel*

OSTI-LLNL-QIP-2.1, *Establishment and Verification of Required Education and Experience of Personnel*

OSTI-LLNL-QIP-4.0, *Procurement Document Control*

OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*

OSTI-LLNL-QIP-6.0, *Controlled Documents*

OSTI-LLNL-QIP-6.1, *Document Review*

OSTI-LLNL-QIP-7.0, *Control of Purchased Products and Services*

OSTI-LLNL-QIP-12.0, *Control of Measuring and Test Equipment and Calibration Standards*

OSTI-LLNL-QIP-17.0, *Records Management*

OSTI-LLNL-QIP-SI.0, *Software Management*

OSTI-LLNL-QIP-SIII.0, *Scientific Notebooks*

OSTI-LLNL-QIP-SIII.3, *Submittal and Incorporation of Data to the Technical Data Management System*

8. ATTACHMENTS

Attachment 1 - OSTI-LLNL Organizational Structure

9. REVISION HISTORY

2/25/05 Revision 0, Modification 0
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10. APPROVALS

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